



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0190]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0671. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, daniel.gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act--(OMB Control Number 0910-0671)--Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111–31) into law. Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section 3(b)(3)(A) of the Smokeless Tobacco Act requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA.

This information collection--the submission to FDA of warning plans for smokeless tobacco products--is statutorily mandated. The warning plans will be reviewed by FDA, as required by the Smokeless Tobacco Act, to determine whether the companies' plans for the equal distribution and display of warning statements on packaging and the quarterly rotation of warning statements in advertising for each brand of smokeless tobacco products comply with section 3 of the Smokeless Tobacco Act, as amended.

Based on the Federal Trade Commission's (FTC's) previous experience with the submission of warning plans and FDA's experience with smokeless tobacco companies (e.g., correspondence associated with user fees under section 919 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act (21 U.S.C. 387s)), FDA estimates that there are 36 companies affected by this information collection. To account for the entry of new smokeless tobacco companies that may be affected by this information collection, FDA is estimating the total number of respondents to be 100.

When the FTC requested an extension of their approved information collection in 2007, based on over 20 years implementing the warning plan requirements and taking into account increased computerization and improvements in electronic communication, the FTC estimated submitting an initial plan would take 60 hours. Based on FDA's experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable.

In the Federal Register of March 18, 2013 (78 FR 16678), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Capital Costs
Submission of rotational plans for health warning label statements	100	1	100	60	6,000	\$1,200

¹ There are no operating and maintenance costs associated with this collection of information.

FDA estimates a total of 100 respondents at 1 response each and 60 burden hours per response for a total of 6,000 burden hours ($100 \text{ respondents} \times 1 \text{ response} \times 60 \text{ burden hours} = 6,000 \text{ total burden hours}$). In addition, capital costs are based on all 100 respondents mailing in their submission at a postage rate of \$12 for a 5-pound parcel (business parcel post mail delivered from the farthest delivery zone). Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to be \$1,200.

Dated: June 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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